

II. Amendments to the Claims

This listing of claims shall replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claims 1-74 (canceled)

Claim 75. (previously presented): A dosage form comprising:
particles, the particles consisting of

- (a) an opioid antagonist;
- (b) hydrophobic means for sequestering the opioid antagonist; and
- (c) one or more optional pharmaceutical excipients;

the hydrophobic means for sequestering the opioid antagonist is such that
an amount of the opioid antagonist released from the dosage form which has been orally
administered intact is less than an amount bioequivalent to 0.125 mg of naltrexone, based on the
in-vitro dissolution at 1 hour of the dosage form in 900 ml of Simulated Gastric Fluid using a
USP Type II (paddle) apparatus at 75 rpm at 37° C, and is insufficient to produce a physiological
effect of the opioid antagonist in a human patient, and

an amount of the opioid antagonist released from the dosage form which has been
subjected to tampering is an amount bioequivalent to 0.25 mg of naltrexone or more, based on
the in-vitro dissolution at 1 hour of the dosage form in 900 ml of Simulated Gastric Fluid using a
USP Type II (paddle) apparatus at 75 rpm at 37° C, and will produce the physiological effect;

wherein the tampering is by crushing, shearing, grinding, chewing, dissolving in a
solvent, heating, or any combination thereof; and

wherein the intact dosage form releases less than 15% by weight of the opioid antagonist
within 36 hours, based on the in-vitro dissolution in a dissolution bath, and the dosage form is an
oral dosage form.

Claim 76. (previously presented): The dosage form of claim 75, wherein the hydrophobic means
for sequestering comprises a layer comprising a hydrophobic material.

Claim 77. (previously presented): The dosage form of claim 75, wherein the hydrophobic means for sequestering comprises from about 93% to about 98% of a hydrophobic material by weight of the particles.

Claim 78. (previously presented): The dosage form of claim 75, wherein the opioid antagonist is naltrexone, naloxone, nalmefene, cyclazacine, levallorphan, pharmaceutically acceptable salts or mixtures thereof.

Claim 79. (previously presented): The dosage form of claim 75, wherein the ratio of the amount of antagonist released from the dosage form after tampering to the amount of the antagonist released from the intact dosage form is about 4:1 or greater, based on the in-vitro dissolution at 1 hour of the dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37° C.

Claim 80. (previously presented): The dosage form of claim 75, further comprising an opioid agonist in a releasable form, which is separate from the particles.

Claim 81. (previously presented): The dosage form of claim 80 which provides immediate release of the opioid agonist when the dosage form is orally administered.

Claim 82. (previously presented): The dosage form of claim 80 which provides sustained release of the opioid agonist when the dosage form is orally administered.

Claim 83. (previously presented): The dosage form of claim 75 which does not pose a risk of precipitation of withdrawal in opioid tolerant or dependent patients when the dosage form is orally administered intact.

Claim 84. (previously presented): The dosage form of claim 75, wherein the opioid antagonist is not bioavailable when the dosage form is administered intact but is bioavailable when the dosage form is tampered with.

Claim 85. (previously presented): The dosage form of claim 75, wherein the physiologic effect is reversal of the effects of opioids.

Claim 86. (previously presented): The dosage form of claim 75, wherein the tampering is by crushing.

Claim 87-88. (cancelled)

Claim 89 (previously presented): The dosage form of any one of claims 75, 76, 78, 79, 80, 81, or 82, wherein the amount of the antagonist released at 1, 2, 4 and 12 hours from the intact dosage form, based on the in-vitro dissolution in a dissolution bath, is undetectable by High Performance Liquid Chromatography.

Claim 90 (cancelled)

Claim 91 (previously presented): The dosage form of any one of claims 75, 76, 78, 79, 80, 81, or 82, wherein the amount of the antagonist released from the dosage form which has been administered intact is bioequivalent to 0.025 mg of naltrexone or more.

Claim 92 (previously presented): The dosage form of claim 75, wherein the hydrophobic means for sequestering comprises an acrylic polymer.